

REMARKS/ARGUMENTS

In the Office Action dated October 30, 2008, the Examiner rejected pending claims 36-54 on prior art grounds. More specifically, claims 36, 37, 43, 44, 49 and 50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0085950 to Robitaille et al.; and claims 38-42, 45-48 and 51-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Robitaille et al.

In general, the present invention is directed to an apparatus and method for humidifying a sterilization chamber which, unlike the prior art, controls thermal energy in the system using a stepped humidification process. That is, the invention provides for graduated humidification by discrete steps. To this end, the thermal energy is controlled so that the chamber temperature remains substantially constant, i.e., a preferred chamber temperature is maintained. Independent claims 36, 44 and 51 have been amended to more fully bring out the differences between the present invention and prior art, as will now be discussed in more detail below.

The co-owned Robitaille et al. reference teaches providing water for the humidification from a source at a temperature which will be above its boiling point when exposed to the reduced pressure of the chamber. Thus, when the source is exposed to the lower pressure of the chamber, it boils and the resulting vapor enters the chamber to provide humidity. However, what was found in practice, if one follows the teaching of Robitaille et al., is that the boiling of the water naturally cools down the water source. In practice, the target humidity cannot be achieved in one step and, therefore, before more humidity can be provided to the chamber, the source must be reheated. However, after heating the source and repeating this cycle, it is found that the necessary heating introduces substantial thermal energy into the system which causes the chamber temperature to rise. See paragraph 0014 of the Applicant's U.S. Patent Publication No. 2007/003429 (present invention), discussing the temperature problem. Since humidity is temperature dependent, more water is needed to give the same relative humidity value at

a higher temperature. This negative cycle results in failed sterilizations, and thus uncertainty in the effectiveness of the sterilization.

The reason for such failures was found to be the large amount of additional thermal energy needed to reheat the water after the boiling. However, that was not previously realized. Initially, it was believed that simply boiling the water was all that was necessary to provide the target humidity. When difficulty was encountered to reach the target humidity, the valve connecting the chamber atmosphere to the source was repeatedly opened and closed in an attempt to evaporate sufficient water to reach the target. This is the procedure which is described in Robitaille et al. at paragraph 0064. However, this was found to produce somewhat "hit or miss" results, and did not provide the level of certainty desirable for clinical sterilization. Further, ozone sterilization is so dependent on precise control of humidity, that other types of sterilization offered no solutions.

The present inventor realized that the problem was the thermal energy input which was resulting in the undesirable increases in chamber temperature which, in turn, led to the lack of control of the process, and discovered that the process could be brought back under control if one discarded the assumption that the target humidity could be reached in one step, or as quickly as possible. Specifically, he realized that by increasing the humidity in discrete steps, the chamber temperature could be controlled since one could control any additional thermal energy introduced into the system by way of heating the water source. There is no teaching in the Robitaille et al. reference which suggests controlling the temperature differential between the reservoir and the chamber in order to maintain the chamber temperature substantially constant. Not only is Robitaille et al. silent about such control, Applicant respectfully submits that it was in no way obvious from the teaching of Robitaille et al..

The humidity problem associated with the practice of Robitaille et al. appeared to be unsolvable until the present inventor came up with the solution provided in the subject application. In any case, in order to more fully bring out the differences between the

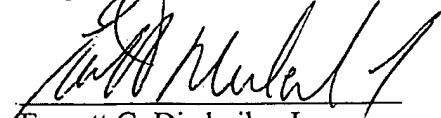
present invention and the prior art, amendments have been made to independent claims 36 and 44. More specifically, claim 36 now requires that the conduit between the reservoir and the sterilization chamber is closed for a time sufficient to adjust the temperature of the reservoir (T_s) to be equal to or above the chamber temperature (T_c), and controlling a temperature differential (ΔT) during each step c) to maintain the chamber temperature (T_c) substantially constant. While Robitaille et al. does discuss lowering the boiling point of water to below the temperature in the sterilization chamber to effect evaporation of water into the humidifier (see paragraph 0039), and a heating device that maintains the temperature of water in the humidifier chamber sufficiently high to achieve a higher water vapour evaporation rate (see paragraph 0052), Robitaille et al. does not teach controlling a temperature differential ΔT during each repeated step c) to maintain the chamber temperature substantially constant. Similarly, claim 44 was amended to require that step b) comprises disconnecting the source from an enclosed space for a time sufficient to adjust T_s or T_c to achieve the value for ΔT_x and controlling the temperature differential ΔT to maintain T_c substantially constant. These features are simply not found in Robitaille et al.

With respect to the Examiner's rejection of claims 43 and 50, the Examiner notes that Robitaille et al. teaches that condensation on articles within the chamber is prevented by repeated evacuation of the chamber and intermediate flushing with ambient air or oxygen at ambient temperature. See paragraph 0050 of Robitaille et al. However, Robitaille et al. does not teach repeating steps b) and c), i.e., reducing pressure into the chamber and bringing the reservoir into fluid communication with the chamber, while disconnecting the fluid communication after a preselected exposure time, wherein the increase in relative humidity in the chamber is selected to avoid substantially any condensation in the chamber as required by claim 43. Similarly, Robitaille et al. does not teach that the number of stages and corresponding water vapour pressure values are selected to avoid substantially any condensation in the enclosed space, as required by claim 50.

The Examiner's rejection of claims 38-42, 45-48 and 51-54 under 35 U.S.C. § 103(a) will now be addressed. Similar to claims 36 and 44, independent claim 51 has been amended to require that the processor be programmed to effect a humidification of the sterilization chamber in a plurality of stages and to control a temperature difference between the first and second heating means to maintain the temperature of the chamber substantially constant. Robitaille et al. does not teach such a limitation. At most, Robitaille et al. teaches that a valve 34 is preferably opened and closed several times for a pre-set period of time to **control the increasing rate of the relative humidity** inside the chamber. See paragraph 0064 of Robitaille et al. As mentioned above, the opening and closing of the valve was done in an attempt to evaporate sufficient water to reach the target, but does control a temperature differential as required by the present invention. Simply stated, Robitaille et al. does not recognize the problem solved by the present invention or function in accordance with the present invention as now claimed. To this end, it would not be obvious for one of ordinary skill in the art to control the temperature of the Robitaille et al. system in the manner required by the present invention.

Based on the above remarks and amendments to the claims, it is respectfully submitted that the present invention is patentably defined over the prior art of record such that allowance of all claims and passage of the application to issue are respectfully requested. If the Examiner should have any additional questions or concerns regarding this matter, the Examiner is cordially invited to contact the undersigned at the number provided below in order to further prosecution.

Respectfully submitted,



Everett G. Diederiks, Jr.
Attorney for Applicant
Reg. No. 33,323

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DIEDERIKS & WHITELAW, PLC
12471 Dillingham Square, #301
Woodbridge, VA 22192
Tel: (703) 583-8300
Fax: (703) 583-8301